ARNOLD & PORTER LLP

202.942.5000 202.942.5999 Fax

555 Twelfth Street, NW Washington, DC 20004-1206



November 16, 2004

Office of Initial Patent Examination **Filing Receipt Corrections**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Application No. 10/741,534

Filed: December 19, 2003

Title: Compositions for the Treatment and Prevention of

Nephropathy

Inventors: Alain BARON et al. Atty. Docket: 18528.675 / 0218-UTL-9

Sir:

The following documents are submitted herewith for appropriate action by the U.S. Patent and Trademark Office (PTO):

- 1. a Request for Corrected Official Filing Receipt;
- 2. a copy of the Updated Filing Receipt with corrections indicated in red;
- 3. copies of Combined Declarations and Powers of Attorney for Patent Application executed by inventors Alain Baron, David R. Hathaway, Mahesh Mistry and Richard J. Roman previously submitted on June 21, 2004;
- 4. a copy of a Preliminary Amendment previously submitted on June 21, 2004; and
- 5. a return postcard.

Please stamp the attached postcard with the filing date of these documents and return it to our courier.

Applicants do not believe any fees are due in conjunction with this filing. However, if any fees are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter LLP Deposit

ARNOLD & PORTER LLP

Commissioner for Patents

Atty. Docket: 18528.675 / 0218-UTL-9 Appln. No. 10/741,534

Page 2

Account No. 50-2387, referencing matter number 18528.675. A duplicate copy of this letter is enclosed.

Respectfully submitted,

David R. Marsh (Reg. No. 41,408) Milan M. Vinnola (Reg. No. 45,979)

Thomas E. Holsten (Reg. No. 46,098)

Attachments



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit: 1614

plication of:

Alain BARON et al.

Application No.: 10/741,534 Atty. Docket No.: 18528.675

Filed: December 19, 2003 Confirmation No.: 5134

For: Compositions for the Treatment and

Prevention of Nephropathy

REQUEST FOR CORRECTED OFFICIAL FILING RECEIPT

Office of Initial Patent Examination Filing Receipt Corrections

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Attached is a copy of the official filing receipt from the United States Patent and Trademark Office for the above-referenced application for which issuance of a corrected filing receipt is respectfully requested. There is an error with respect to the priority data.

Please make the following corrections to the section entitled "Domestic Priority data as claimed by applicant". A marked-up version of the Official Filing Receipt is attached.

"This appln claims benefit of 10/740,146 12/17/2003 which claims benefit of 60/434,508 12/17/2002 and claims benefit of 60/434,888 filed 12/19/2002"

In support of this correction, enclosed are copies of the Combined Declarations and Powers of Attorney for Patent Application executed by inventors Alain Baron, David R.

Alain BARON et al.

Page 2

Appln. No.: 10/741,534

Hathaway, Mahesh Mistry, and Richard J. Roman that were filed with the U.S. Patent and Trademark Office on June 21, 2004. These Declarations list Provisional Application Serial Nos. 60/434,508, 60/434,888, and Non-Provisional Application Serial No. 10/740,146 for purposes of priority. In further support, enclosed is a copy of the Preliminary Amendment filed June 21, 2004 to update the cross-reference to related applications.

Applicants believe that no fee is due. However, if any charges are deemed appropriate, authorization to charge such fees is given in the accompanying transmittal letter.

Respectfully submitted,

David R. Marsh (Reg. No. 41,408) Milan M. Vinnola (Reg. No. 45,979)

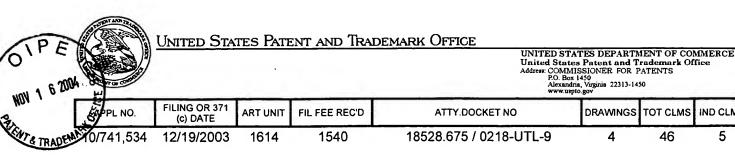
Thomas E. Holsten (Reg. No. 46,098

Date: November 16, 2004

ARNOLD & PORTER LLP 555 Twelfth Street, N.W. Washington, D.C. 20004-1206 (202) 942-5000 telephone (202) 942-5999 facsimile

IND CLMS

5



28381 ARNOLD & PORTER LLP ATTN: IP DOCKETING DEPT. 555 TWELFTH STREET, N.W. WASHINGTON, DC 20004-1206

CONFIRMATION NO. 5134 UPDATED FILING RECEIPT *OC000000013198667*

TOT CLMS

46

Date Mailed: 07/12/2004

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Alain Baron, San Diego, CA; David R. Hathaway, Lincoln, NE; Mahesh Mistry, Pepperell, MA; Richard J. Roman, Brookfield, WI;

Domestic Priority data as claimed by applicant 12/11/2003

This appln claims benefit of 69/434;688 12/19/2002

which claims benefif of 60/434.508 12/17/2002

Foreign Applications Claims benefit of 60/434 888.

If Required, Foreign Filing License Granted: 03/31/2004

Projected Publication Date: 10/21/2004

Non-Publication Request: No

Early Publication Request: No

JUL 1 4 2004 DOCKET DEP ARNOLD & PORTER WASHINGTON, DC

Title

Compositions for the treatment and prevention of nephropathy

LICENSE FOR FOREIGN FILING UNDER Title 35, United States Code, Section 184 Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).



Combined Declaration and Power of Attorney for Patent Application

Docket Number: 18528.675

below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed and for which a patent is sought on the invention entitled Compositions for the Treatment and Prevention of Nephropathy, the specification of which is attached hereto unless the following box is checked:

\boxtimes	was filed on Dece	<u>mber 19, 2003;</u> Application Number <u>10/741,53</u> 4	4; and	
	was amended on _	(if	applicable).	
hereby	state that I have reas amended by any	eviewed and understand the con amendment referred to above.	ntents of the above identified specific	ation, including the
I acknov	wledge the duty to	disclose information that is ma	terial to patentability as defined in 37	C.F.R. § 1.56.
patent o country invento	r inventor's certific	cate, or § 365(a) of any PCT in	§ 119(a)-(d) or § 365(b) of any foreig ternational application, which designates we also identified below any foreign a ving a filing date before that of the appropriate that the appropriate the appropriate that the appropriate the appropriate that the appropriate that the appro	pplication for patent or
Prior Fo	oreign Application	(s)		Priority Claimed
(Applic	eation No.)	(Country)	(Day/Month/Year Filed)	☐ Yes ☐ No
(Applic	cation No.)	(Country)	(Day/Month/Year Filed)	☐ Yes ☐ No
I hereb	y claim the benefit	under 35 U.S.C. § 119(e) of an	ny United States provisional applicati	on(s) listed below.
	<u>/434,508</u> cation No.)	December 17, 2002 (Filing Date)		
	0/434,888 cation No.)	December 19, 2002 (Filing Date)		

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or under § 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information that is material to patentability as defined in 37 C.F.R. § 1.56 that became available between the filing date of the prior application and the national or PCT international filing date of this application.

10/740,146 (Application No.)	December 17, 2003 (Filing Date)	Pending (Status - patented, pending, abandoned)
(Application No.)	(Filing Date)	(Status - patented, pending, abandoned)
(Application No.)	(Filing Date)	(Status - patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

practitioners at Arnold & Porter LLP, Customer No. 28381;

and

Holman, Molly A., Reg. No. 40,022 Butler, James E., Reg. No. 40,931 Kim, Mi, Reg. No. 44,830 Moore, Joanna, Reg. No. 44,950

All of Amylin Pharmaceuticals, Inc.

Send Correspondence to:

David R. Marsh ARNOLD & PORTER LLP

Attn: IP Docketing Dept. 555 12th Street, N.W. Washington, D.C. 20004-1206 Facsimile: (202) 942-5999

Direct Telephone Calls to: (202) 942-5000

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor: Alain BARON
Inventor's signature Adir Pune of June of
Residence San Diego, California
Citizenship United States of America
Post Office Address 12863 Baywind Point
San Diego, California 92130
Full name of second inventor: David R. HATHAWAY
Inventor's signature Date
Residence Lincoln, Nebraska
Citizenship United States of America
Post Office Address 6201 Oaks Hollow Road
Lincoln, Nebraska 68516
Full name of third inventor: Mahesh MISTRY
Inventor's signature Date
Residence Pepperell, Massachusetts .
Citizenship United States of America
Post Office Address 31 Prospect Street
Pepperell, Massachusetts 01463

Full name of fourth inventor: Richard J. ROMAN				
Inventor's signature	I	Date		
Residence Broo	kfield, Wisconsin			
Citizenship U	Inited States of America			
Post Office Address 32	270 Dartmouth Drive			
Ві	rookfield, Wisconsin 53005			
Full name of fifth inventor:				
Inventor's signature		Date		
Residence				
Citizenship U	Jnited States of America			
Post Office Address				
Full name of sixth inventor	:			
Inventor's signature		Date		
Residence				
Citizenship (United States of America			
Post Office Address				



Combined Declaration and Power of Attorney for Patent Application

Docket Number: 18528.675

below named inventor, I hereby declare that:

was filed on December 19, 2003;

 \boxtimes

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed and for which a patent is sought on the invention entitled Compositions for the Treatment and Prevention of Nephropathy, the specification of which is attached hereto unless the following box is checked:

	tes Application Number <u>10/741,</u> on			
I hereby state that I ha claims, as amended by	ve reviewed and understand the any amendment referred to abo	contents of the above identified specific ve.	cation, includir	ig the
I acknowledge the duty	y to disclose information that is	material to patentability as defined in 37	7 C.F.R. § 1.56	j.
patent or inventor's cer country other than the	rtificate, or § 365(a) of any PCT United States listed below, and	C. § 119(a)-(d) or § 365(b) of any foreig international application, which design have also identified below any foreign a having a filing date before that of the approximate the approximate of the approximate that the app	ated at least or application for	ie patent oi
Prior Foreign Applica	tion(s)		Priority	Claimed
(Application No.)	(Country)	(Day/Month/Year Filed)	☐ Yes	☐ No
(Application No.)	(Country)	(Day/Month/Year Filed)	☐ Yes	□ No
I hereby claim the ben	nefit under 35 U.S.C. § 119(e) of	any United States provisional application	on(s) listed bel	ow.
60/434,508 (Application No.)	December 17, 200 (Filing Date)	12	. •	
60/434,888 (Application No.)	December 19, 200 (Filing Date))2		

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or under § 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information that is material to patentability as defined in 37 C.F.R. § 1.56 that became available between the filing date of the prior application and the national or PCT international filing date of this application.

Application No. 10/741,534 Docket No. 18528.675

10/740,146 (Application No.)	December 17, 2003 (Filing Date)	Pending (Status - patented, pending, abandoned)
(Application No.)	(Filing Date)	(Status - patented, pending, abandoned)
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nventor's signature Date
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Post Office Address 12863 Baywind Point
San Diego, California 92130
Full name of second inventor: David R. HATHAWAY
Inventor's signature WM. Javny MS Date 6/2/04
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Citizenship United States of America
Post Office Address 6201 Oaks Hollow Road
Lincoln, Nebraska 68516
Full name of third inventor: Mahesh MISTRY
Inventor's signature Date
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Pepperell, Massachusetts 01463

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Inventor's signature		Date		
Residence				
Citizenship	United States of America			
Post Office Address				
Full name of sixth invent	or:			
Inventor's signature		Date		
Residence				
Citizenship	United States of America			
Post Office Address				
		,		



Combined Declaration and Power of Attorney for Patent Application

Docket Number: <u>18528.675</u>

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\boxtimes	was filed on Dece	ember 19, 2003; Application Number <u>10/741,534</u>	1; and	
	was amended on	(if	applicable).	
I hereby claims,	state that I have roas amended by any	eviewed and understand the con amendment referred to above.	ntents of the above identified specific	ation, including the
l acknov	wledge the duty to	disclose information that is mat	terial to patentability as defined in 37	C.F.R. § 1.56.
patent o country invento	r inventor's certific	cate, or § 365(a) of any PCT int ited States listed below, and hav	119(a)-(d) or § 365(b) of any foreig ternational application, which design we also identified below any foreign a wing a filing date before that of the ap	ated at least one pplication for patent or
Prior Fo	oreign Application	(s)		Priority Claimed
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10/740,146 (Application No.)	December 17, 2003 (Filing Date)	Pending (Status - patented, pending, abandoned)
(Application No.)	(Filling Date)	(Glatas - paternous, periamis, acantoones)
(Application No.)	(Filing Date)	(Status - patented, pending, abandoned)
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Inventor's signature Muhish Mith Date 02 June, 2004				
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Application No. 10/741,534 Docket No. 18528.675

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Combined Declaration and Power of Attorney for Patent Application

Docket Number: <u>18528.675</u>

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as United Stat was amended	tes Application Number <u>10/74</u> on	<u>1,534;</u> and _ (if applicable).	
I hereby state that I have claims, as amended by	ve reviewed and understand the any amendment referred to ab	e contents of the above identified specific love.	cation, including the
I acknowledge the duty	y to disclose information that i	s material to patentability as defined in 3	7 C.F.R. § 1.56.
patent or inventor's cer	rtificate, or § 365(a) of any PC United States listed below, and	.C. § 119(a)-(d) or § 365(b) of any foreig T international application, which design d have also identified below any foreign in having a filing date before that of the a	ated at least one application for patent or
Prior Foreign Applicat	tion(s)	·	Priority Claimed
(Application No.)	(Country)	(Day/Month/Year Filed)	☐ Yes ☐ No
(Application No.)	(Country)	(Day/Month/Year Filed)	☐ Yes ☐ No
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60/434,888 (Application No.)	December 19, 2 (Filing Date)	002	

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Inventor's signature Juland Jaman	Date 5/31/04			
Residence Brookfield, Wisconsin				
Citizenship United States of America				
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Brookfield, Wisconsin 53005				
Full name of fifth inventor:				
Inventor's signature	Date			
Residence				
Citizenship United States of America				
Post Office Address				
Full name of sixth inventor:				
Inventor's signature	Date			
Residence				
Citizenship United States of America				
Post Office Address				



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Alain BARON et al.

Appln. No.: 10/741,534

December 19, 2003 Filed:

For: Compositions for the Treatment and

Prevention of Nephropathy

Art Unit:

1614

Atty. Docket:

18528.675/0218-UTL-9

Confirm. No.: 5134

Preliminary Amendment

Mail Stop Missing Parts Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Prior to examination on the merits, please enter the following amendment.

Amendments

In the specification:

On page 1 of the specification, please **replace** the section entitled "CROSS REFERENCE TO RELATED APPLICATIONS" with the following **amended** paragraph:

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of priority to U.S. Serial No. 10/740,146 [[_____]], entitled "Prevention and Treatment of Cardiac Arrhythmias," filed December 17, 2003, which claims priority to U.S. Provisional Application No. 60/434,508, filed December 17, 2002; and U.S. Provisional Application No. 60/434,888, filed December 19, 2002, all of which are incorporated herein by reference in their entirety.

On page 1 of the specification, please **insert** the following paragraph before the heading "FIELD OF THE INVENTION":

INCORPORATION OF SEQUENCE LISTING

A paper copy of the Sequence Listing and a computer readable form of the sequence listing on diskette, containing the file named 18528.675.seqlist.txt, which is 34,038 bytes in size (measured in MS-DOS), recorded and filed on June 21, 2004, are hereby incorporated by reference.

Remarks

By this Preliminary Amendment, the specification has been amended to update the cross reference to related applications by providing the application number of the first mentioned U.S. application. Further, the specification has been amended to provide the reference to the Sequence Listing. No new matter has been entered by this amendment.

Respectfully-submitted,

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Date: June 21, 2004

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